UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,868	09/30/2003	Michael Slivka	DEP-5170	7650

27777 7590 05/27/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,868	SLIVKA ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 14-41* is/are pending in the application.

4a) Of the above claim(s) *8-11,15 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,12,14,16-18 and 20-41* is/are rejected.

7)☒ Claim(s) *5,17,18 and 20-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants filed an appeal brief on 28 January 2008, and a supplemental appeal brief correcting an informality on 27 February 2008, appealing the Final Rejection mailed 26 November 2007. However, upon reconsideration the finality of the last office action is being withdrawn, **PROSECUTION IS HEREBY REOPENED.** New grounds of rejection are set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111; or

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then Appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Election/Restrictions

A review of the prosecution shows that it is not clear which claims are under consideration and which have been withdrawn as being directed to non-elected species. For clarity of the record, the following is presented:

On 21 March 2006 a restriction requirement was mailed, requiring election of (1) A type of Repair Material; (2) Type of cells seeded in Cell-Seeded Material; (3) Type of Autologous Medium to be Combined with Material; and (4) Type of Bioactive Factor to be Combined with Material.

On 17 April 2006, Applicants elected, with traverse, the species (1) Small Intestinal Submucosa (SIS); (2) cells from spinal discs; (3) bone marrow; and (4) GDF-5. The traversal was on the grounds that the burden placed on Applicants to prosecute multiple patent applications far outweighs the additional burden placed on the Examiner to do any additional searching.

On 6 July 2006, the Examiner replied that the reasons for traverse were unpersuasive because the burden on a single examiner with limited resources and very limited time is undue. The restriction/election requirement was deemed proper and made FINAL.

Currently claims 1, 4-7, 12, 14, 16-18 and 20-41 read on the elected species and have been considered on the merits. Claims 1, 4-12 and 14-41 remain pending in the current application, of which claims 8-11, 15 and 19 are withdrawn from consideration as being directed to non-elected species, there being no allowable generic or linking claim.

Response to Arguments

Applicant's arguments filed 26 November 2007, with respect to the rejection(s) of all claims under 35 USC 112, first paragraph, as lacking enablement have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection are set forth below.

Claim Objections

Claim 5 is objected to form a minor informality: it appears claim 5 should read, "The method of claim 4, wherein the biocompatible material is a bioabsorbable or non bioabsorbable material." Correction is required.

Claims 17, 18, 20 and 21-40 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Specifically, claim 17 should refer to "The method of any one of claims 1, 4-7, [[12-14]] 12, 14, and 16... " It is further noted that claim 13 is cancelled, and thus should not be referenced by pending claims. Claims 18 and 26-31 ultimately depend from claim 17, and are therefore objected to on the same grounds.

Claim 20 should refer to "The method of any one of claims [[1-16]] 1, 4-7, 12, and 14-16…" It is noted that claims 2, 3 and 13 are cancelled, and thus should not be referenced by pending claims. Claims 22, 32-34 and 38-40 ultimately depend from claim 20, and are therefore objected to on the same grounds.

Claim 21 should refer to "The method of any one of claims 1, 4-7, [[12-14]] 12, 14, and 16... " It is further noted that claim 13 is cancelled, and thus should not be referenced by pending claims. Claims 35-37 ultimately depend from claim 21, and are therefore objected to on the same grounds.

Claim 23 should refer to "The method of any one of claims [[1-16]] 1, 4-7, 12, and 14-16…" It is noted that claims 2, 3 and 13 are cancelled, and thus should not be referenced by pending claims. Claims 24 and 25 ultimately depend from claim 23, and are therefore objected to on the same grounds.

Correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d

887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-7, 17, 18, 23-31 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 11-14 of copending Application No. 10/676,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the co-pending claims anticipate current claims 1, 4-7, 17, 18 and 23-31, in that the co-pending claims recite the same method of treatment, yet are narrowed to use of SIS. It is noted that co-pending claim 3 recites the SIS is to be in an elongated form, which may include 'strip form'. The co-pending claims recite the SIS implant material may be seeded with the same cell types currently claimed, as well as the presence of the same bioactive agents.

With regards to current claim 41, while the co-pending claims do not recite forming the SIS implant into a mushroom shape, it is submitted that differences in the shape of a product, when the shape would be routinely optimized based on the recognized use/need, are considered to be obvious. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)*. Thus, depending on the defect shape and configuration, manipulation of the SIS implant material into any necessary shape, including a mushroom shape, would have been well within the purview of the artisan of ordinary skill, and thus rendering the instant claim 41 *prima facie* obvious over the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 5, 17, 18, 23, 24, 26, 27, 29 and 30 are rejected under 35 USC 102(b) as being anticipated by Gan et al (US Patent 5,964,807).

Gan et al disclose a method for repairing spinal disc defects, comprising removing damaged tissue from the nucleus pulposus (which reads on what Applicants call preparing a disc treatment site), preparing a hybrid material of intervertebral cells and a biodegradable substrate material; and inserting the hybrid material into the intervertebral space to be repaired (See col. 5, ln 12-22). The hybrid material can be provided in any shape for insertion into the intervertebral disc space of a patient, Gan et al specifically disclose a substrate having a rectangular shape (See col. 9, ln 18-30). In the absence of a more limiting definition, the word 'strip' is being given its normal definition as: "**strip (noun):** 1 a**:** a long narrow piece of a material" (Merriam-Webster Online Dictionary "Strip", URL: http://www.m-w.com/dictionary/strip accessed 5/15/08). Thus, the rectangular shaped hybrid material of Gan et al is considered to read on a 'substantially two-dimensionally shaped disc defect repair material in the form of a strip', thus insertion of such into the intervertebral disc space reads on the method of claim 1.

The biodegradable substrate material may be selected from bioactive glass, polymer foam, or polymer foam coated with sol gel bioactive materials (See col. 6, ln 30-32). Materials made from bioactive glass or polymer foam may be porous (See col. 6, ln 53-60, col. 7, ln 27-33). The intervertebral disc cells seeded on the biodegradable substrate material may include nucleus pulposus cells (which read

on what Applicants call cells obtained from spinal discs) (See col. 8, 50-61). Bioactive factors, including transforming growth factor-beta may be further provided in the biodegradable implant material (See col. 8, ln 62-col. 9, ln 5).

Therefore the reference anticipates the claimed subject matter.

Claims 1, 4-7, 17 and 26 are rejected under 35 USC 102(e) as being anticipated by Bilbo (US 2007/0250177).

Bilbo discloses tissue engineered grafts, and methods of implanting the tissue engineered grafts to repair, augment or replace natural tissue structures in need thereof (See Pg. 2, paragraph 0010). In Example 13 Bilbo disclose repairing the annulus fibrosis (part of the intervertebral disc) by performing a discectomy (which reads on what Applicants call preparing a disc treatment site), providing a bioengineered flat sheet of ICL prosthesis (which reads on providing a disc repair material), and inserting the bioengineered flat sheet ICL into the annular hole opening (which reads on inserting the repair material into the disc to be repaired) (See Pg. 14, paragraph 0120-0124). The bioengineered flat sheet of ICL prosthesis was made of small intestinal submucosa (SIS) (See Pgs. 9-10, paragraphs 0070-0082). In the absence of a more limiting definition, the word 'strip' is being given its normal definition as: "**strip (noun):** 1 a: a long narrow piece of a material" (Merriam-Webster Online Dictionary "Strip", URL: http://www.m-w.com/dictionary/strip accessed 5/15/08). Thus, the flat sheets of ICL used by Bilbo are considered to read on a 'substantially two-dimensionally shaped disc defect repair material in the form of a strip', thus insertion of such into the intervertebral disc space reads on the method of claim 1. SIS is naturally porous, biocompatible and bioresorbable.

The ICL can further include bioactive agents, such as collagen, extracellular matrix components, growth factors, and/or seeded with cells (See Pg. 6, paragraph 0043 & Pg 8, paragraphs 0052-0056).

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-7, 12, 14, 16-18 and 20-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (US Patent 5,964,807), in view of Bilbo (US 2007/0250177), Li et al (US Patent 6,764,514), Lim et al (WO 03/51239), and Moehlenbruck et al (US Patent 6,723,335).

Gan et al disclose a method for repairing spinal disc defects, comprising removing damaged tissue from the nucleus pulposus (preparing a disc treatment site), preparing a hybrid material of intervertebral cells, such as nucleus pulposus cells, and a biodegradable substrate material (providing a cell-seeded defect repair material); and inserting the hybrid material into the intervertebral space to be repaired (See col. 5, ln 12-22).

With regards to the shape of the hybrid material (defect repair material), Gan et al state the hybrid treatment material can be shaped as necessary for insertion into the defect (See Gan et al col. 9, ln 19-31); Gan et al recite a disc shape (Fig. 1), as well as a rectangular shape or a cylindrical pad. The rectangular form of Gan et al has been considered to read on the recited 'substantially two-dimensionally shaped disc defect repair material in the form of a strip' (as discussed above). However, even if the rectangular form of Gan et al is not one and the same as that currently claimed, it is submitted that modification of the defect repair material of Gan et al into a form suitable for implantation into the intervertebral disc defect, including the form of a substantially two-dimensional strip, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have clearly optimized the shape of the repair material so as to correlate as closely as possible with the defect

site to be repaired. One would have had a reasonable expectation of manipulating the shape of the repair material of Gan et al based on the fact that Gan et al clearly state the shape of the hybrid material can be manipulated, thus Gan et al shows manipulating the shape of the defect repair material was within the skill of the ordinary artisan. It has been held that differences in the shape of a material, when the shape would be routinely optimized based on the recognized use/need, are considered to be obvious. See *In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)*. For the same reasons, it is further submitted that manipulation of the hybrid repair material of Gan et al into the form of a mushroom shape, if the defect site to be repaired has a mushroom shape, would be *prima facie* obvious.

Gan et al differs from some aspects of the instant invention in that they do not disclose using SIS as the substrate for the hybrid material. However, SIS was known as a suitable graft material for use in tissue defect repair, including for repair of intervertebral discs, see, e.g. Bilbo. Bilbo disclose bioengineered grafts comprised of ICL (derived from porcine SIS) for implantation into intervertebral disc defect sites (See Bilbo, Pg. 14, paragraphs 0120-0124). Like the hybrid materials of Gan et al, the ICL grafts of Bilbo can be seeded with cells and/or bioactive factors, including growth factors.

It has been held that substitution of a known element for another to yield predictable results would have been obvious to one of ordinary skill in the art. In the instant case, both Gan et al and Bilbo report methods for repairing damaged intervertebral discs, by removing the damage disc, and inserting a defect repair material into the defect site, each of the repair materials yield the same result: occlusion of the defect site, permitting regeneration of natural tissue. Thus, substitution of the SIS (as disclosed by Bilbo) for the substrate material of the hybrid material in Gan et al, would have been obvious to one of ordinary skill in the art.

Gan et al differs from some aspects of the instant invention in that while they disclose implanting the repair material into the disc defect, they do not specifically state the repair material is twisted or manipulated as part of the insertion step. However, it is submitted that one of ordinary skill in the art will recognize that twisting, folding, or otherwise manipulating the repair material may be necessary in order to successfully insert the material into the defect site (See, *e.g.* Li et al, as they disclose rolling, curling or folding (all which read on twisting) an implant material to accommodate insertion into a cavity through a small opening, at col. 4, ln 40-55). Clearly if the opening made to the intervertebral disc space is smaller than the actual repair material, it would be necessary to fold, or twist the repair material in order to manipulate it through the opening into the defect site. The substrate materials disclosed by Gan et al, particularly the polymer foams, as well as SIS, if substituted as the substrate material, are recognized by the artisan as being flexible, and thus one would have a reasonable expectation that the materials could be manipulated, twisted or folded as necessary.

Gan et al differs from some aspects of the instant invention in that, while they disclose including bioactive factors, including transforming growth factor-beta, in the biodegradable implant material (See col. 8, ln 62-col. 9, ln 5), they do not specify the growth factor GDF-5. It is noted that Gan et al teach growth factors, including transforming growth factor-beta enhances cell growth (See Gan et al, col. 8, ln 62-66). A person of ordinary skill, in reading Gan et al, would have recognized the desirability of improving cell growth within the hybrid material. Lim et al teaches that GDF-5 is one of a finite number of growth factors included in the transforming growth factor-beta family, known to be useful for promoting cartilage growth (chondroinductive properties) (See Lim et al, Pg. 7, ln 9-23). Thus, it would have been obvious to a person of ordinary skill in the art to try GDF-5 as the particular transforming growth factor-beta protein provided to the hybrid material of Gan et al in an attempt to provide improved cell growth within the hybrid material of Gan et al upon implantation. It has been held that "a person with

ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." See *KSR International Co. v Teleflex, Inc.* 82 USPQ2d 1385 at 1390.

Finally, Gan et al differs from some aspects of the instant invention in that they do not disclose combining the repair material with autologous bone marrow prior to insertion into the defect site. However, at the time the invention was made, it was known in the art to be beneficial to include autologous bone marrow in intervertebral disc implant materials to increase regeneration *in situ* (See, e.g. Moehlenbruck et al, col. 5, ln 6-30); thus one of ordinary skill would have been motivated to further apply autologous bone marrow to the implant material of Gan et al, for the predictable result of increasing regeneration of the disc tissue *in situ*. One would have had a reasonable expectation of successfully providing and applying bone marrow to the implant material of Gan et al because Moehlenbruck et al disclose that use of bone marrow in intervertebral disc implants was within the purview of the artisan of ordinary skill (See Moehlenbruck et al, col. 5, ln 6-30).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651